

REMARKS

Claims 24-30 are pending in the present application. Claims 14-23 have been withdrawn. Claims 24-30 have been added. Reconsideration of the claims is respectfully requested.

The claimed gel composition, comprising carboxymethylcellulose from 0.01 to 10.0%; propylene glycol from 0.001 to 50.0%; methylparaben from 0.001 to 3.0%, and 4-nerolidylcatechol from 0.005 to 20.0% is fully supported by the specification ([0030] to [0034]). The preparation of the composition itself is not specifically described in the specification, however it is mentioned that the composition of this invention can be made through any known methods in the pharmacy art [0037]. Additionally, the specification mentions that a possible source for 4-nerolidylcatechol is a *Pothomorphe umbellata* root extract [0029]. Although it is not specifically mentioned in the specification, someone skilled in the art would know that 4-nerolidylcatechol could be obtained by any other means (other plant extracts, organic synthesis etc).

Examples 1 and 2 in the specification show the effect of the topical application of a gel containing 0.1% 4-nerolidylcatechol. Example 1 teaches that topical of a gel containing 0.1% 4-nerolidylcatechol preserved the levels of α -tocopherol in the skin of irradiated mice, thus protecting it against degradation from the UV radiation [0044]. Example 2 teaches that topical of a gel containing 4-nerolidylcatechol in the concentration of 0.1% reduced photoaging in the skin of UV irradiated mice [0048].

No relevant prior reference teaches a gel composition comprising 0.005 to 20.0% of 4-nerolidylcatechol therein.

Two references, published by the inventors themselves, do teach of a topical gel composition comprising an extract of *Pothomorphe umbellata*, wherein the gel compositions comprises 0.1% 4-nerolidylcatechol (on the basis of the *Pothomorphe umbellata* extract) therein.

However, both references should be not be considered by the Examiner as prior art as they have been published by the inventors themselves within the grace period of the present application.

The reference Ropke et al. (Intl. J. Pharmaceutics, December 2002) was published in December 2002, i.e. nine months prior to the filing of the US application which was filed for on

September 17th 2003, as a PCT application and is undoubtedly not regarded as prior art to this application.

Likewise, the reference Ropke et al. (Free Radical Biol. Med., Vol 33, Issue 2, Abstract #527, 15 July 2002, was published by the inventors themselves, two months prior to the filing of the Brazilian priority application (PI0204130-8) which was filed on September 18th, 2002.

It must also be noted that the reference Ropke et al. (Annals of the 14th National Cosmetology Congress of the Brazilian Cosmetology Assoc, 2000), which is indeed considered prior art to the present invention does not teach of a topical composition presented in a gel form as previously suggested by the Examiner (Office Action, December 5, 2007, p.17). This reference specifically teaches of an oil/water emulsion comprising an extract of *Pothomorphe umbellata* and not a gel composition.

Some of the prior art cited by the Examiner also makes reference to *Pothomorphe umbellata* extracts. Uchiyama (JP2001122763) teaches of a topical skin composition comprising an extract of *Pothomorphe umbellata*, but does not teach of a composition specifically containing 4-nerolidylcatechol.

Similarly none of the above references expressly of teach therapeutic methods comprising topically administering a gel composition comprising 0.005 to 20.0% of 4-nerolidylcatechol therein.

Given that a prior art reference anticipates the claimed invention under 35 U.S.C. §102 only if every element of a claimed invention is identically shown in that single reference, arranged as they are in the claims and that the references mentioned above fail to teach or suggest the claimed invention, the new set of claims should be considered novel.

Given the references above, at the time the claimed invention, it would not have been obvious to one of ordinary skill in the art how exactly to incorporate 4-nerolidylcatechol (obtained from a *Pothomorphe umbellata* extract or any other source) into a gel composition. That is to say, it would not be obvious as to what specific gel formulation to use in order to obtain a therapeutically effective gel composition. First of all, it would not be obvious as to what specific combination of common skin gel components to use in such gel composition comprising 4-nerolidylcatechol. Secondly, it would surely not be obvious as to what quantities of each of the components should be used in said gel composition.

In fact, it must be noted that it is the specific combination of the components of the

claimed gel composition that grant its therapeutic properties.

It well known in the art that a given antioxidant must permeate active compound must permeate the stratum corneum and reach the viable skin to exert its antioxidant activity. This permeation depends not only on the structure of the antioxidant compound itself but also on the specific formulation used and the interaction between the compound itself and the formulation used with the skin. The topical skin composition taught by Uchiyama (JP2001122763) was only tested *in vitro* and it is therefore impossible to predict from his work as to what specific gel composition comprising an extract of *Pothomorphe umbellata* and/or 4—nerolidylcatechol would exhibit the desired permeability essential for therapeutic purposes. Example 1 of the specification demonstrates that the claimed composition has indeed the ability to deliver 4—nerolidylcatechol into the skin (FIG. 3) and can therefore be used topically for therapeutic purposes.

Additionally, in order to exhibit photoprotective properties, a given antioxidant must be photostable after UV exposure. Previous studies of *Pothomorphe umbellata* extracts have not employed UV radiation and it was thus not obvious at time of the claimed invention as to which specific formulation containing an extract of *Pothomorphe umbellata* and/or 4—nerolidylcatechol would be photostable. The results shown in Example 2 demonstrate that the claimed composition is capable of protecting the skin against UV radiation after UV exposure and therefore exhibits the desired photostability properties (FIG. 5).

The original title of the patent application, “Use of Pothomorphe Umbellata Extract, Composition on Basis Of Pothomorphe Umbellata Extract and Method of Application Of the Pothomorphe Umbellata Extract” no longer makes sense in view of the new set of claims. We suggest that you alter the title to “Gel composition comprising 4-nerolidylcatechol and uses thereof”.

Please note that on both Office Actions, dated April 23, 2007 and December 5, 2007, the Examiner requested a copy of the prior art document Ropke, 1999 as cited in pages 6 and 7 of the specification. This specific reference is in fact the Masters Dissertation of Dr. Ropke. The matter disclosed in this reference is the same as that disclosed in Ropke et al. (Annals of the 14th National Cosmetology Congress of the Brazilian Cosmetology Assoc, 2000), cited above.

The dissertation is 83 pages long and is written in Portuguese. Unfortunately, Monday (February 4th) and Tuesday (February 5th) are national holidays in Brazil and there will be no

post, DHL or FedEx services available. We will be posting the dissertation by FedEx on Wednesday, 6th and it should arrive in your office by Thursday 7th. Please respond to the Office Action by February 5th and inform the Examiner that the requested reference will follow promptly.

CONCLUSION

In light of the amendments and the arguments made by Applicants above, as well as the evidence previously submitted, Applicants submit that all existing, examined claims are now in a condition for allowance. Applicants respectfully request that Examiner withdraw all restrictions and rejections with regard to the above-referenced claims in reliance on one or more of the grounds submitted by Applicants.

If there are any outstanding issues that the Examiner feels may be resolved by way of telephone conference, the Examiner is invited to call David Carstens at the below-listed telephone number if in the opinion of the examiner such a telephone conference would expedite or aid the prosecution and examination of this application.

The Commissioner is hereby authorized to charge any payments that may be due or credit any overpayments to CARSTENS & CAHOON, LLP Deposit Account 50-0392.

Respectfully submitted,

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